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مشـــروع تـــعزيـــز تنظيـــم الأســـرة
Strengthening Family Planning Project

SHOPS
Strengthening Health Outcomes through the Private Sector

Depo-Provera

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Learning Objectives

Participants will be able to know:

1. **The indications and contraindication of depo-provera**
2. **Formulation and pharmacology**
3. **Mechanism of action and failure rate**
4. **Benefits and side effects**
5. **Administration and managing late injections**

Counseling

- **Information**
- **Access**
- **Choice**
- **Safety**
- **Privacy**
- **Confidentiality**
- **Dignity**
- **Comfort**
- **Continuity**
- **Opinion**

G — Greet

A — Ask

T — Tell

H — Help

E — Explain

R — Return

Counseling

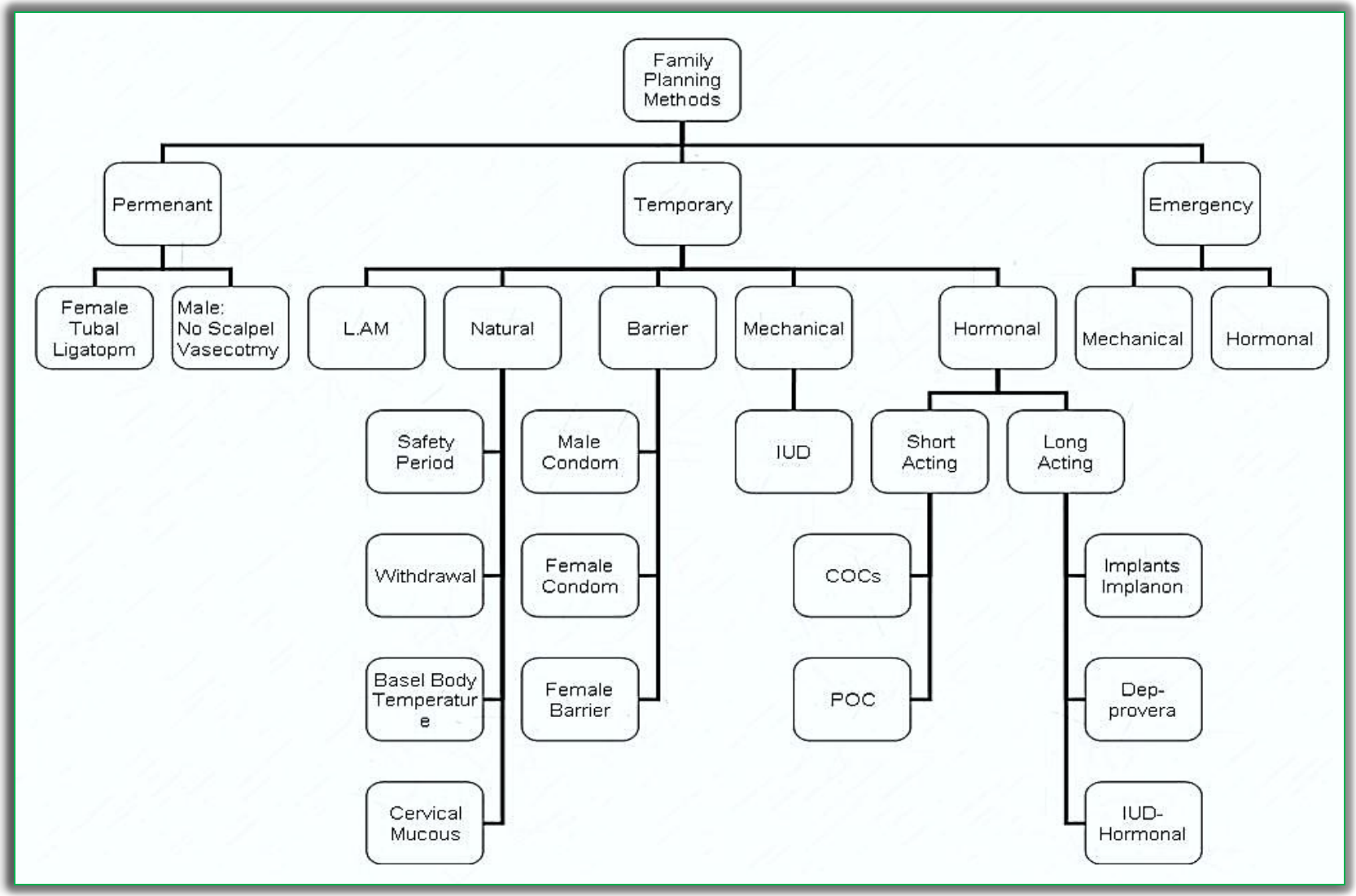
- Counsel the woman in a **private place.**
- Ask the woman about her **reproductive plans**.
- Ask the woman about her **previous family planning experiences**.
- Tell the woman what family planning **choices** are available in the market
- Ask the woman which family planning (FP) method **interests her** most.
- Take detailed personal and medical **history** keeping in mind the contraindications to each method.

- After history taking and before deciding which FP method is appropriate, perform a minimum of the following:

  - Blood pressure measurement.
  - Body mass index.
  - Breast exam if you are going to prescribe hormonal methods.
  - Perform a pelvic exam and look for RTI/STI and pelvic anomalies if you are going to insert an IUD.

- Based on the history and physical findings, tell the woman which methods are medically suitable for her (refer to WHO MEC chart/wheel)
- If she has no preference, suggest a method based on her medical history, past use and reproductive plans.
- Provide a brief description of the major methods that are medically suitable to the woman.

Family Planning Methods



Period of protection

Method	Effective for . . .
Pills	As long as the pill is taken.
IUD	Up to 10 years for the copper IUD, 5 years for the Levonorgestrel releasing Device (hormonal IUD).
Injectable (depo-provera)	As long as the injection is taken and each one lasts 3 months.
Condoms	Only for the single act when used.
Implants	3-5 years. Implanon is effective for 3 years.
Vaginal ring (NuvaRing)	As long as it is used.
LAM	Up to 6 months

How used?

Method	Usage
Pills	Taken daily either 21 or 28 days each month throughout the year.
IUD	Placed in the uterus by a doctor.
Injectable	Injected in the arm or hip every three months.
Condoms	Used by male partner at the time of each sexual intercourse.
Implants	Placed by a doctor under the skin of arm.
Vaginal ring (NuvaRing)	Inserted intravaginally by the woman.

Mode of action

Method	Mechanism of action
COCs	Prevent ovulation
POPs	Increase viscosity of cervical mucous thus prevent sperms from meeting eggs. Prevent ovulation.
Cu-T-IUD	Works primarily by releasing chemicals that kill sperms and prevents the sperm from fertilizing the egg.
LNG-IUS	Suppresses the growth of lining endometrium
Injectable	Prevents ovulation, inhibits endometrial proliferation Increases viscosity of cervical mucous
Condom	Prevents sperm from entering vagina.
Implants	Thicken cervical mucous, prevent ovulation.
Vaginal ring (NuvaRing)	Suppression of ovulation and inhibition of endometrial proliferation

Efficacy

Method	Efficacy
COCs	99%
POPs	99% for breastfeeding women 90-97% for non breastfeeding women
Cu-T-IUD	More than 99%
LNG-IUS	99.8%
DMPA Injection	More than 99%
Condom	85%
Implants	99.95%
Female sterilization	99.5%
Vasectomy	97-98%
Vaginal ring (NuvaRing)	Research on effectiveness is limited

Major advantages

Method	Advantages
COCs	• Very effective when used correctly. • Can be used at any age. • No delay in return to fertility once stopped. • Regulates the menstrual period. • Protects againts endometrial and ovarian cancers. • Prevents some illnesses like ovarian cysts, symptoms of polycytic ovaries (e.g. hisutism, acne, irregular bleeding), menstrual cramps and iron deficiency anemia.
POP	• Does not interfere with milk supply. • No estrogen side effects. • No delay in return to fertility once stopped.
CuT-IUD	• Very effective long term method. • Easily removed. • No delay in return to fertility after removal. • No hormonal side effects. • No effect on breast milk. • Does not need reminder.
LNG-IUS	• Protects against iron deficiency anemia. • Reduces menstrual cramps. • Reduces symptoms of endometriosis.

Major advantages

Injectable	• Very effective. • No need to remember to take daily. • Does not interfere with milk supply. • Protects against endometrial cancer. • Prevents some diseases like sickle cell crisis.
Condoms	• Prevent Sexually Transmitted Infections. • No side effects. • Do not need to see health provider.
Impants	• Effective. • Long lasting. • No need to remember taking. • Protect against symptomatic pelvic inflammatory disease. • May help protect against iron deficincy anemia.
Vaginal ring (NuvaRing)	• Rapid return to fertility after discontinuation. • Lower doses of hormones. • Ease and convenience. • Improved cycle control.

DMPA (DepoProvera) Injection

- Depot medroxyprogesterone acetate (DMPA) is an injectable, progestin contraceptive

  - Highly effective
  - Long-acting
  - Reversible
  - Avoids both the need for user action daily or near the time of sexual intercourse and the need for partner cooperation.

- Other types of progestin contraceptives include:
  - Progestin pills (minipills)
  - Progestin implants (eg, Implanon, Jadelle)
  - Intrauterine contraception (eg, Mirena)

Formulations and Pharmacology

- DMPA is available in two formulations:
  - 150 mg/1 mL for intramuscular injection (IM)
  - 104 mg/0.65 mL for subcutaneous (SC) injection.

  The every three-month injection schedule provides high contraceptive efficacy because low solubility of the microcrystals at the injection site allow pharmacologically active drug levels to persist for several months.

- Following a single 150 mg IM dose of DMPA:
  - Drug levels increase for approximately three weeks
  - Reaching a peak concentration of 1 to 7 ng/ml
  - Undetectable (less than 100 pg/mL) between 120 and 200 days following the injection
  - Ovulation resumes at MPA levels <100 ng/mL .

Formulations and Pharmacology

- The newer 104 mg formulation:
  - Provides slower and more sustained absorption of the progestin than conventional IM DMPA, which allows for a 30% lower dose of progestin
  - With the same duration of effect as conventional DMPA.
  - Administration via the SC route is less painful and may allow patient self-administration.
  - *IM DMPA is available as a generic formulation, which is less costly than DMPA-SC.*
  - The benefits and risks are similar for IM and SC administration.

Mechanism of Action

- DMPA primarily acts by ***inhibition of gonadotropin secretion***, thereby ***inhibiting follicular maturation and ovulation***;

  a hypoestrogenic state results.

- Inhibition of endometrial proliferation renders the **endometrium less suitable for implantation**. Another contraceptive effect is progestin's ability to cause ***changes in cervical mucus and tubal motility*** that are unfavorable to sperm migration, thus inhibiting fertilization.

Failure Rates

- For the 150 mg IM injection, failure rates in clinical trials ranged from 0.0 to 0.7/100 woman-years. The typical-user failure rate is 5/100 woman-years in the first year of use, reflecting that some users do not return for their injections as. Because progestin levels are high, efficacy is not reduced by high body weight or use of concurrent medications.

- For the 104 mg SC injection, no contraceptive failures were reported in phase III clinical trials. This formulation is relatively new; typical-user failure rates are not yet available, but would be expected to be similar to the IM preparation.

Timing of First Injection

Method DMPA	Timing
First injection	
Spontaneous menstrual cycle	Within five days of menses onset
Spontaneous or elective first-trimester abortion	Within seven days
Term delivery	Within three weeks postpartum if not lactating; within six weeks postpartum if lactating
Switching from combination OCs	While on active pills or within seven days after taking the pill pack's last active tablet
Switching from combination contraceptive patch	While on weekly patch or within seven days after patch removal
Switching from combination contraceptive vaginal ring (NuvaRing®)	While ring is in place or within seven days after ring removal
Switching from levonorgestrel IUD (Mirena®)	First injection should occur before IUD removal and within five years after IUD insertion; if patient is menstruating, a condom should be used as back-up if the first injection is not given within 5 days of menses onset
Switching from Copper T 380A IUD	First injection should occur before IUD removal and within 10 years after IUD insertion; a condom should be used as a back-up if the first injection is not given within five days of menses onset

Subsequent Injections

Subsequent injections	
Injection interval	Every 12 weeks or three months; earlier reinjections are acceptable
Grace period	Two weeks; after one week manufacturer recommends pregnancy testing before repeat injection Subsequent studies have suggested that a grace period as long as four weeks is reasonable, and the World Health Organization has adopted the longer grace period in its updated guideline

Managing Late Injections

- If the woman is less than 2 weeks late, she can receive her next injection. No need for tests, evaluations or backup methods.

- More than 2 weeks, she can receive her injection with a backup method for 7 days if the at least one of the following have been met:
  - She did not have sexual intercourse sex since 2 weeks.
  - She used a backup method since 2 weeks.
  - Fully or near fully breast feeding and she gave birth less than 6 months ago.

- More than 2 weeks and does not meet the above criteria; she can receive the injection once pregnancy is excluded.

Switching to Another Method

- The new method should be started no later than 12 to 14 weeks after the previous injection. This ensures that the patient is not pregnant at the time she initiates a new contraceptive method.

- With long-term use of DMPA, most users become amenorrheic. Menstrual status, however, does not determine when DMPA users should start a new birth control method.

Side effects

- Menstrual irregularities (bleeding or amenorrhea),
- Weight changes
- Headache
- Abdominal pain or discomfort
- Nervousness
- Dizziness
- Asthenia

A change in uterine bleeding patterns is the best documented and most common side effect.

Menstrual Changes

- Menstrual changes occur in all women using DMPA and are the most frequent cause for discontinuation.
- During the first months of use, episodes of unpredictable bleeding and spotting lasting 7 days or longer are common. The frequency and duration of such unscheduled bleeding decrease with increasing duration of use.
- With ongoing use, the rate of amenorrhea increases to 75%.
- If persistent spotting one option is to administer estrogen supplements. Another option is to treat spotting or unscheduled bleeding by shortening the interval between injections.

Menstrual Changes

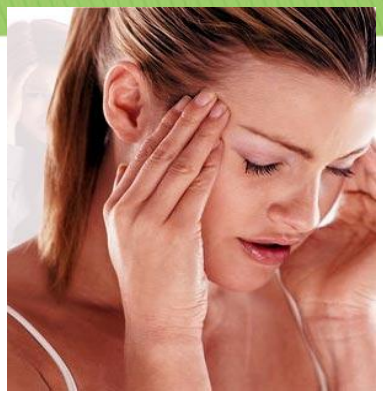
- If bothersome spotting and/or unscheduled bleeding persist after several injections of DMPA, evaluate for anatomic causes of abnormal bleeding unrelated to DMPA use, such as uterine fibroids, adenomyosis or endometrial polyps.

- If a treatable abnormality is not found and the patient remains dissatisfied with the menstrual changes caused by DMPA, then she may be better served by another contraceptive method.

Weight changes

- Some studies found nonsignificant changes in weight among women who used DMPA for up to one year. Others described weight gain ranging from 3 to 6 kg .

- It appears that large weight gain is more likely in certain subgroups, such as adolescents.
  A systematic review found that obese adolescent, but not adult, DMPA users gained more weight than normal weight users. However, even nonobese adolescent DMPA users appear to gain more weight than adolescent nonusers or oral contraceptive users



- **Headache** — DMPA can trigger headache as a side effect in susceptible patients, but progestins prevent migraine in others.
- **Mood changes** —
  - Observational studies have not reported any consistent effects of DMPA on mood.
  - Progestins may cause or exacerbate depressive symptoms in certain subpopulations of women, including those with a history of premenstrual syndrome or mood disorders.
  - Follow such women closely when any progestin-based therapy is initiated
  - History of depression is a not contraindication to use of DMPA.

Benefits

- Used to manage a variety of gynecologic and nongynecologic disorders
- Appropriate contraceptive choice for women with menorrhagia, dysmenorrhea, or iron-deficiency anemia .
- May prevent development of hemorrhagic corpus luteum cysts in women on anticoagulant .SC and IM injections do not appear to increase the risk of local hematoma formation.
- DMPA transforms proliferative into secretory endometrium, thus it protects against development of endometrial hyperplasia.

Benefits

- DMPA users have a decreased risk of PID. This may be related to changes in cervical mucus and decreased menstrual blood flow.
- Very low risk of ectopic.
- For treatment of pain associated with endometriosis. Progestins inhibit endometriotic tissue growth by directly causing initial decidualization and eventual atrophy and by inhibiting pituitary gonadotropin secretion and ovarian estrogen production. DMPA is more effective than estrogen-progestin contraceptives and danazol, and as effective as leuprolide for treatment of pain associated with endometriosis.
- Lack of drug interactions compared to other types of hormonal contraception

Benefits

- Appropriate for individuals with special needs to control cycle (eg, cognitive impairment, military personnel)
- Use of DMPA has been associated with hematologic improvement (fewer painful crises) in women with sickle cell disease.
- DMPA might be a good contraceptive of choice for many women with seizure disorders.
  - The efficacy of DMPA's contraceptive protection does not appear attenuated by the use of enzyme-inducing anticonvulsants.
  - DMPA may have intrinsic anticonvulsant properties.
- DMPA offers effective treatment of menopausal vasomotor symptoms in women who need to avoid estrogen therapy.

Effect on cancer risk

- The WHO examined the risk of endometrial, ovarian, liver, and cervical carcinoma in DMPA-users.
  - DMPA decreased the prevalence of endometrial cancer by 80% (greater protective effect against endometrial cancer than Ocs).
  - Did not increase the risk of ovarian, cervical, or liver cancer.

- Additional data from New Zealand, South Africa and the United States showed no increase in risk of breast cancer in DMPA users.

- Theoretically, it is possible that prolonged ovulation suppression associated with DMPA might provide protection against ovarian cancer, as seen with Ocs.

Effect on cardiovascular risk

- DMPA use reduces plasma HDL and peripheral arterial hyperemia-induced flow-mediated dilatation (FMD), but does not increase production of coagulation factors, and has no adverse effect on blood pressure. Epidemiological studies have **not observed an increase in adverse cardiovascular effects** (venous thrombosis, stroke, acute myocardial infarction) related to past or current DMPA use.
- May be appropriate contraceptive options for women with a history of venous thromboembolism (VTE) and those in whom use of estrogen-progestin contraceptives is contraindicated.
- For women with multiple risk factors for cardiovascular disease (eg, smoking, older age, hypertension, diabetes), women with a history of stroke or ischemic heart disease, and women with a current VTE, the WHO classifies DMPA as Category 3.

Effect on bone mineral density

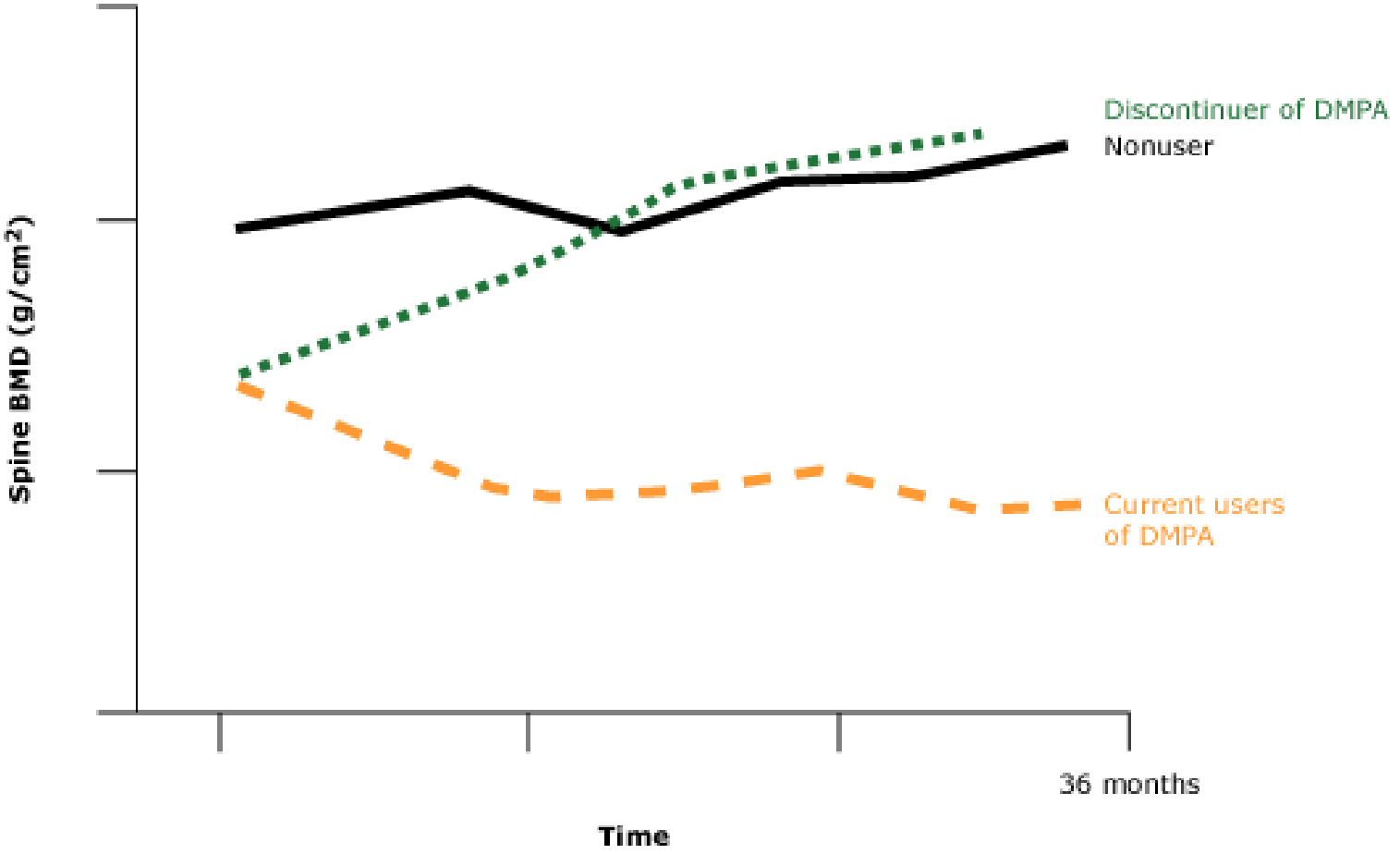
- In hypoestrogenemic states, bone resorption exceeds bone formation, resulting in a decline in bone mineral density (BMD). Compared to nonusers, BMD at the hip and spine of DMPA users decreases by
  - 0.5 to 3.5% after one year and
  - 5.7 to 7.5% after two years of use.

  The rate of loss is not linear; the greatest loss is during the first one to two years of use.

  The SC and IM formulations have similar effects

  - The best available data show that DMPA use does not reduce peak bone mass and does not increase the risk of osteoporotic fracture in later life in women at average risk of osteoporosis.

BMD during/after DMPA use in adult



Data from: Scholes, D, LaCroix, AZ, Ichikawa, LE, et al. Injectable hormone contraception and bone density: results from a prospective study. Epidemiology 2002; 13:581. Copyright ©2002 Lippincott Williams and Wilkins.

Effect on bone mineral density

- In summary, although there is an association between DMPA use and decreased BMD, there is no high quality evidence of a significant increase in risk of fractures in DMPA users .
- In younger women in particular, there are few data on the effect of BMD changes on short- or long-term fracture risk.
- The American College of Obstetricians and Gynecologists, the Society for Adolescent Medicine, the World Health Organization, and the Society of Obstetricians and Gynaecologists of Canada believe that the advantages of DMPA use as a contraceptive generally outweigh the theoretical concerns regarding skeletal harm
- Reversal at the spine occurred sooner, and appeared to be more complete, than reversal at the hip.

Effect on bone mineral density

- Skeletal health concerns should not restrict initiation or continuation of DMPA in adolescent girls, women 18 to 45 years of age, or older reproductive age women.

- The available evidence also does not justify limiting the duration of DMPA therapy, which may be continued for decades.

- Given that the effect of DMPA on BMD is similar to that with pregnancy (decrease in BMD of 2 to 8 percent) or lactation (decrease in BMD of 3 to 5 percent), use of DMPA is not an indication for BMD testing either before, during, or in follow-up of its administration.

Effect on bone mineral density

- Insufficient evidence to provide specific clinical guidance regarding estrogen supplementation for DMPA users, because it appears that estrogen from an exogenous (supplemental estrogen) or endogenous (ovarian) source results in similar recovery of BMD following DMPA discontinuation.
- There are no data on use of other antiresorptive agents (eg, bisphosphonates, calcitonin, selective estrogen receptor modulators) to prevent bone loss in DMPA users. We recommend not using them for this indication.
- Providers should advise DMPA users to ensure adequate intake of calcium and vitamin and engage in regular exercise to promote bone health, which is good advice for all women, regardless of their contraceptive choice.

Contraindications to DMPA.

If any of the following is found, advise the woman to choose another contraceptive method:

- **Breast feeding**; exclusively breast feeding an infant less than six weeks of age.
- **CVS;** Blood pressure above 160/100 or vascular disease, acute DVT/PE (not recommended).
- **GI;** active hepatitis/ liver tumors and cirrhosis.
- **Endocrine;** diabetes more than 20 years or with vascular complications (not recommended).
- **Reproductive:** unexplained vaginal bleeding (prior to evaluation).
- **Rheumatology**: like systemic lupus erythematosus with positive or unknown antiphospholipids antibodies, severe throbocytopenia.
- **Cancer**; presence or history of breast cancer.

Return To Fertility

- Return of fertility may be delayed.
- Within 10 months of the last injection, 50% of women who discontinue DMPA to become pregnant will conceive;
- In a small proportion of women fertility is not reestablished until 18 months after the last injection.
- The persistence of ovulation suppression following DMPA discontinuation is not related to the duration of use, but is related to weight. Women with lower body weights conceive sooner than women with higher body weights after discontinuing DMPA.
- Counsel candidates about the possible prolonged duration of action. Women who may want to become pregnant within the next one or two years should choose an alternative contraceptive.

Administration

- Wash hands and dry with a clean towel.
- Shake vial gently.
- Open the vial.
- Use a 21 or 23 gauge IM needle/ 2 or 5 ml syringe.
- Fill the syringe with proper dose: 150 mg.
- Inject the needle deep into the upper arm (deltoid muscle) or hip (gluteal muscle/ in the upper outer portion).
- **Do not massage or rub** the injection site (causes rapid absorption).

Warning signs ACHES

symptoms that require medical attention:

- Bothersome extremely heavy bleeding (may be alleviated by giving the woman estrogen).
- Severe headache with blurring of vision.
- Chest/ abdominal pain.
- Jaundice.

THANK YOU!

Thank You!

Thank You!

Thank You!